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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,220	11/15/2001	Alan John Kingsman	674523-2011	8450

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NEW YORK, NY 10151

EXAMINER

BROWN, STACY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/17/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/001,220

Applicant(s)

KINGSMAN ET AL.

Examiner

Stacy S Brown

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 11,12,14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10,13 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 6) ☐ Other:

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DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-10, 13 and 16-18 is acknowledged and entered. Claims 1-18 are pending. Claims 1-10, 13, and 16-18 are examined on the merits. Claims 11, 12, 14 and 15 are withdrawn from consideration being drawn to non-elected inventions. Applicants mainly argue that the restriction requirement is improper because no serious burden has been established with regard to examination of all groups. In response, the Office notes that while the composition of claims 11 and 12 may be obtained by the method of claim 10, the claims are drawn to products and therefore the process by which they are obtained is not given patentable weight. The nucleic acid is a different invention because it is structurally different from the compositions of retrovirus and producer cells. For the above reasons and reasons of record, the search and examination of all Groups would be burdensome. Therefore, the restriction is deemed proper and made FINAL.

Priority

2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

The Office notes that a statement regarding priority exists in the file on a separate sheet of paper, unattached to any amendment or instructions for entering into the specification. Accordingly, this statement has not been entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing an infectious retrovirus comprising an amphotropic envelope polypeptide in a producer cell, does not reasonably provide enablement for enhancing the production of an infectious retrovirus comprising an ecotropic envelope polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The breadth of the claims is unreasonable, encompassing the production of retrovirus comprising ecotropic envelope polypeptide. The claims also encompass the "enhancing" of a production method. Neither of these two embodiments is enabled by Applicant's specification. The nature of the invention is drawn to retrovirus production in producer cells, comprising down-regulating an endogenous receptor in order to allow viral production in the cells without interference with the endogenous receptor. Applicants disclose that the binding of the envelope protein to the receptor causes a reduction in the retroviral titre produced by the producer cell

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(specification, page 9, last paragraph). Applicants also disclose that 293T producer cells do not express receptors for the ecotropic envelope (page 21, line 6) and one can therefore conclude that the method would not be expected to work for retroviruses comprising an ecotropic envelope polypeptide. The state of the art shows that transduction by an amphotropic retrovirus vector requires high-level expression of the retrovirus receptor Pit2 (Kurre *et al*, *J. Virology*, 1999, cited in IDS). Kurre found that over expression of the Pit2 receptor increased transduction efficiency (abstract of Kurre). The level of predictability in the art is low, given the teachings of Applicants and Kurre which appear to conflict with each other. Kurre's overexpression of the Pit2 receptor increased transduction efficiency, whereas Applicant's down-regulation of Pit2 receptor increased viral production. The amount of guidance and direction in the specification leads one of skill in the art to produce an infectious retrovirus comprising an amphotropic envelope polypeptide in a producer cell. The specification's summary of data (page 21) is limited and appears only to deduce the fact from negative data that the envelope is a limiting factor in viral production. *Applicant is requested to clarify any misunderstanding of the data presented on page 21 of the specification.* Therefore, given the unreasonable breadth of the claims, the low level of predictability, the lack of guidance, and the state of the prior art, the claims are not enabled by the specification for their full scope.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-10, 13, 16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 and dependent claims 2-10, 13 and 16, “enhancing the production” is unclear because there is no comparative basis for “enhancing”.
- Claim 4 and dependent claims 5-8 and claim 18, “effecting the cleavage” is unclear. What is meant by “effecting” and how does one know that “effecting” has occurred? Clarification is requested.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Combadiere et al (WO97/45543). The claims are drawn to a producer cell in which an endogenous receptor's expression or activity is inhibited. Combadiere provides antibodies and peptides that block HIV interaction with CCR5 receptors (page 4, lines 1-7). Cell lines are disclosed on pages 16-17. Therefore, the claims are anticipated by Combadiere, which teaches the inhibition of CCR5 activity, an endogenous receptor of a cell.

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Conclusion

6. Claims 1-10 and 13 are free of the prior art.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SSB

Stacy S. Brown
June 6, 2003

James C. Housel
JAMES HOUSEL 6/16/03
SUPERVISORY PATENT EXAMINER
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